

REMARKS

Claims 1-82 are pending. Claims 1-80 are under examination. Claims 13, 38, 39, 47, 78 and 79 have been amended to correct typographical errors. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Objection to the Claims

Claims 38, 39, 78 and 79 have been objected to because the phrase "is at least compound selected from" is grammatically incorrect. Applicants have amended these claims to recite "at least one compound" to correct the grammatical error. Accordingly, it is respectfully requested that this objection be removed.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1-80 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. Applicants submit that these claims are clear and definite.

Claims 1, 13, 14, 41, 47, 48, 52 and 56 stand rejected as allegedly indefinite for the term "isoflavone synergist." Applicants submit that this term is clear and definite. As taught in the specification, an isoflavone synergist is a compound that has a synergistic effect in the presence of isoflavones (paragraphs 72-75, pages 20-21). In view of the teachings in the specification, Applicants maintain that this term is clear and definite and respectfully request that this rejection be withdrawn.

Claims 1, 19, 22, 25, 41, 60, 61, 64 and 67 stand rejected as allegedly indefinite for the phrase "methylation support compound." Applicants submit that this term is clear and definite. As taught in the specification, a methylation support compound refers to a compound that supports methylation of estrogenic metabolites (paragraphs 76-77, pages 21-22). Applicants maintain that this term is clear and definite and respectfully request that this rejection be withdrawn.

Claims 5, 8, 9, 18, 25-30, 33, 34, 42, 43, 62, 67-72 and 74 stand rejected as allegedly indefinite for the term "derivative." Applicants submit that this term is clear and definite. The specification teaches various types of derivatives, for example, derivatives of 2-hydroxyestradiol (paragraph 76, page 21), tocotrienol derivatives (paragraph 85, page 24), folic acid derivatives (paragraph 91, page 26), cobalamin derivatives (paragraph 98, page 30) and estrogen derivatives (paragraph 160, page 55). Based on the teachings in the specification, one skilled in the art would readily understand the meaning of "derivative." Accordingly, Applicants maintain that the term "derivative" is clear and definite and respectfully request that this rejection be withdrawn.

Claims 6 and 7 stand rejected as allegedly indefinite for the term "lipid modulator." Applicants submit that this term is clear and definite. The specification teaches the meaning of a fat (lipid) modulator (paragraphs 57-58, page 16). Based on the teachings in the specification, one skilled in the art would readily understand the meaning of a lipid modulator. Accordingly, Applicants maintain that this term is clear and definite and respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

The rejection of claims 1-80 under 35 U.S.C. § 103 as allegedly obvious over Cope, U.S. Patent No. 5,330,972, in view of Clark et al., U.S. Patent No. 5,837,256, and Yang et al., U.S. publication 2002/0025360. Applicants respectfully submit that the claims are unobvious over Cope, alone or in combination with Clark et al. and/or Yang et al.

With regard to Cope, this reference describes a high protein, low fat, calorically dense product for HIV infected and AIDS patients (paragraph bridging columns 4 and 5 and columns 5 and 6). The Office Action acknowledges that Cope does not teach a composition comprising all of the claimed ingredients, and in particular indicates that Cope does not describe sources of dietary fiber, flavonoid and isoflavone synergist. The Office Action asserts that Clark et al. teaches a composition comprising flaxseed lignan. The Office Action further acknowledges that neither of Cope or Clark et al. teaches a composition comprising curcumin, lycopene, hesperidin

or quercetin. However, the Office Action asserts that Yang et al. teaches a food composition comprising curumin, lycopene, hesperidin or quercetin.

Applicants respectfully disagree with the assertion in the Office Action on page 5, second paragraph, that an “artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited references teaches a composition comprising macronutrient and micronutrient components recited in the claimed invention.” In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify or to combine the reference teachings. Applicants respectfully submit that there is no motivation in any of the prior art references to combine ingredients with those described in the other references to make Applicants’ claimed invention. In particular, Cope provides no teaching or motivation to look beyond its own disclosure of a nutritional product for HIV infected and AIDS patients and provides no motivation to look for additional components to combine to obtain the claimed invention.

Furthermore, Clark et al. provides no teaching or motivation to look beyond its own disclosure of the use of secoisolariciresinol derived from flaxseed to treat lupus nephritis to obtain Applicants’ claimed invention. Thus, neither of Cope or Clark et al. provide any motivation to combine teachings directed to a nutritional product for AIDS patients and a method for treating lupus nephritis. Moreover, Yang et al. provides no teaching or motivation to look beyond its own disclosure of a chewy confectionery composition to obtain Applicants’ claimed invention. Not only are these three references directed to completely different uses, thus providing no motivation to look at these unrelated references to obtain the claimed invention, none of the references provide any indication of a deficiency that would have motivated one skilled in the art to look at any of the other references to supply the missing deficiency. Absent any teaching or suggestion to combine the cited references, Applicants submit that the claims are unobvious over the cited references.

Applicants respectfully submit that it is only with the hindsight benefit of Applicants’ disclosure that the combination of Cope, Clark et al. and Yang et al. can be advanced. It is well established that Applicants’ disclosure cannot be used to hunt through the prior art for the

claimed elements and then combine them as claimed (In re Laskowski, 871 F.2d 115, 117; 10 USPQ 2d 1397, 1398 (Fed. Cir. 1989). Hindsight cannot be used to resolve the questions of obviousness (Orthopedic Equipment Co., Inc. v United States 702 F.2d 1005, 1012 (Fed. Cir. 1983)):

[t]he difficulty which attaches to all honest attempts to answer this question [non-obviousness] can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.

Applicants respectfully submit that the only way the disclosures of Cope, Clark et al. and Yang et al. can be read to result in the claimed medical food is with benefit of Applicants' disclosure. Such hindsight application of Applicants' disclosure is clearly improper. Absent the teachings in Applicants' disclosure, there is no teaching or suggestion in any of the cited references to motivate one skilled in the art to combine the cited references. Absent such a teaching or suggestion, it is respectfully submitted that the claimed medical foods are unobvious over Cope, Clark et al. and/or Yang et al. Accordingly, Applicants respectfully request that this rejection be withdrawn.


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Serial No.: 10/056,858
Filed: January 23, 2002
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CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

Respectfully submitted,

Date: November 20, 2003



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